

WRA

**Wagner Regulatory
Associates, Inc.**

454875-00

P.O. Box 7954
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Hand Delivered

August 17, 2001

Document Processing Desk (APPL)
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7-236-R

Re: DISHWASHER MAGIC® containing Citric Acid -
Application for Registration

On behalf of Dishwasher Magic LLC, I am submitting the enclosed application to register the new product DISHWASHER MAGIC® containing the active ingredient citric acid. It is requested that the Agency approve this application under FIFRA Section 3(c)(7)(A) on the basis that the product DISHWASHER MAGIC® is substantially similar to existing registrations and use patterns currently registered with EPA that contain citric acid.

Please note that EPA issued a Reregistration Eligibility Document (RED) for citric acid in 1992. In the RED, EPA has waived all generic data requirements other than product chemistry, acute toxicity, and product performance. To satisfy the product chemistry data requirements for the technical grade of active ingredient (TGA) of citric acid we have cited the same scientific literature used to support the RED. Ms. Karen Hicks in the Antimicrobial Division confirmed to me on August 15, that citing the RED to satisfy the data requirements for the TGA is acceptable provided that the citric acid in DISHWASHER MAGIC® is manufactured using the same process as discussed in the RED. I have included a certification in this application that this is the case.

Therefore, in support of this application I am submitting the following data and information for Agency review:

ADMINISTRATIVE VOLUME:

- EPA Application Form 8570-1
- Proposed label for DISHWASHER MAGIC® together with a discussion of use conditions
- Certification with Respect to Citation of Data Form 8570-34
- Confidential Statement of Formula Form 8570-4 with MSDS for each inert ingredient
- Data Matrix Form 8570-35
- Letter from Dishwasher Magic LLC appointing Wagner Regulatory Associates, Inc. as agent
- Letter from U.S. EPA assigning Dishwasher Magic LLC company number 74286

Data Transmittal Document

VOLUME 1: Product Identity, Composition and Analysis

VOLUME 2: Physical/Chemical Properties

VOLUME 3: Physical/Chemical Properties of DISHWASHER MAGIC®

VOLUME 4: Physical and Chemical Characteristics: Physical State, pH, Viscosity, and Density/Relative Density

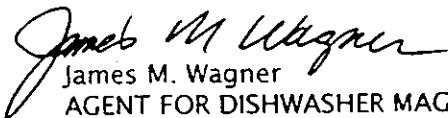
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VOLUME 5: Primary Eye Irritation Study in Rabbits
VOLUME 6: Primary Skin Irritation Study in Rabbits
VOLUME 7: Acute Oral Toxicity Study in Rats - Limit Test
VOLUME 8: Acute Dermal Toxicity Study in Rats - Limit Test
VOLUME 9: Acute Inhalation Toxicity and Skin Sensitization: Request for Data Waivers
VOLUME 10: AOAC Use Dilution Test Broad Spectrum
VOLUME 11: AOAC Use Dilution Test

Please let me know if there is any additional information that you require to complete this registration application. Dishwasher Magic LLC is very anxious to gain EPA registration approval for this product within the next 3 months. We would appreciate anything you can do to expedite the review process.

Please call me if you have any questions about this submission. Thank you for your help with this application.

Respectfully submitted,


James M. Wagner
AGENT FOR DISHWASHER MAGIC LLC

Enclosures

cc: Mr. Kevin Schmidt, Dishwasher Magic LLC
Wyckoff, New Jersey

Mr. Adam Heyward
Product Manager
EPA, OPP
Antimicrobial Division

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Wagner Regulatory Associates, Inc.
Agent for Dishwasher Magic LLC
P.O. Box 7954
Wilmington, DE 19803-0954

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Dishwasher Magic®
EPA Registration Number 74286-

3. Transmittal Date

August 14, 2001

4. List of Submitted Studies

Vol. 1, Wagner, J.M., "Product Identity, Composition, Analysis," Wagner Regulatory Associates, Inc., Wilmington, DE, Report No. WRA-01-001, 30 pages. **45481401**

Vol. 2, Wagner, J.M., "Physical/Chemical Properties," Wagner Regulatory Associates, Inc., Wilmington, DE, Report No. WRA-01-002, 26 pages. **45481402**

Vol. 3, Wagner, J.M., "Physical/Chemical Properties of Dishwasher Magic®", Wagner Regulatory Associates, Inc., Wilmington, DE, Report No. WRA-01-003, 5 pages. **45481403**

Vol. 4, Wo, C., "Physical and Chemical Characteristics: Physical State, pH, Viscosity, and Density/Relative Density," Product Safety Labs, Dayton, NJ, Laboratory Study Number 10667, 14 pages. **45487501**

Vol. 5, Merkel, D.J., "Primary Eye Irritation Study in Rabbits," Product Safety Labs, Dayton, NJ, Laboratory Study Number 10670, 16 pages. **45487502**

Vol. 6, Merkel, D.J., "Primary Skin Irritation Study in Rabbits," Product Safety Labs, Dayton, NJ, Laboratory Study Number 10671, 16 pages. **45487503**

Vol. 7, Merkel, D.J., "Acute Oral Toxicity Study in Rats-Limit Test," Product Safety Labs, Dayton, NJ, Laboratory Study Number 10668, 15 pages. **45481404**

Vol. 8, Merkel, D.J., "Acute Dermal Toxicity Study in Rats-Limit Test," Product Safety Labs, Dayton, NJ, Laboratory Study Number 10669, 16 pages. **45481405**

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List of Submitted Studies, (cont'd)

ADMIN

Vol. 9, Wagner, J.M., "Acute Inhalation Toxicity and Skin Sensitization: Request for Data Waivers", Wagner Regulatory Associates, Inc., Wilmington, DE, Report Number WRA-01-004, 5 pages.

Vol. 10, Suchmann, D.B., "AOAC Use Dilution Test Broad Spectrum," MicroBioTest, Inc., Sterling, VA, Laboratory Project ID Number 464-101, 23 pages. 45481406

Vol. 11, Suchmann, D.B., "AOAC Use Dilution Test," MicroBioTest, Inc., Sterling, VA, Laboratory Project ID Number 464-102, 21 pages.

45481407

Company Official: James M. Wagner

James M. Wagner
5/14/01

Company Name: Wagner Regulatory Associates, Inc.

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